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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/904,045 | 07/12/2001 | John W. Butcher | 20709 | 1941 |

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EXAMINER

CEPERLEY, MARY

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/904,045

Applicant(s)

BUTCHER ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

1) Applicants are requested to clarify which compound has the structure of Formula II.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a radioactive benzopyran compound, classified in class 546, subclass 17.
- II. Claim 4, drawn to a method of determining whether or not a ion channel is an I_{Kr} channel, classified in class 436, subclass 504.
- III. Claims 5-9, drawn to a method of determining whether or not a compound is an I_{Kr} channel blocker, classified in class 436, subclass 804.
- IV. Claims 10-27, drawn to methods of assessing the binding of a test compound to a membrane containing the I_{Kr} channel, classified in class 436, subclass 811.
- V. Claims 28-36, drawn to a method of making a TMSO-substituted benzopyran, classified in class 546, subclass 14.
- VI. Claims 37-39, drawn to a method of making a radioactive benzopyran compound, classified in class 546, subclass 17.
- VII. Claim 40, drawn to a TMOS-substituted benzopyran intermediate, classified in class 546, subclass 14.

3) The inventions are distinct, each from the other because of the following reasons:

a) Inventions VII and I are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as an intermediate to prepare corresponding non-radioactive compound of formula I as described in U.S. patent 5,633,247 and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

b) Inventions I and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product could be made by any of the processes disclosed in U.S. Patent 5,633,247 using the analogous ³⁵S reactant.

c) Inventions **a)** I and **b)** each of II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of I could be used in either of the processes of Invention II or Invention III which use different methodology to make different types of determinations. Additionally, the products of I could be used as antiarrhythmia agents as described in U. S. Patent 5,633,247.

d) Invention **a)** IV and **b)** each of II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

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the instant case the different inventions use different reactants and method steps, Invention IV using the compound of Formula II in addition to the compound of Formula I.

e) Inventions V and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds of VII could be prepared starting with an NH₂- and OH-substituted benzopyran and later adding the spiro-pyridine moiety.

4) Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter requiring different searches in both the patent and technical literature as well as different patentability considerations, restriction for examination purposes as indicated is proper.

5) Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6) Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7) Applicants are advised that in accordance with the court decisions in *In re Ochiai*, {71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995)} and *In re Brouwer* {77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir.

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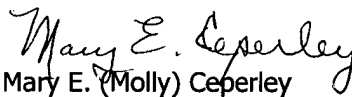
1996)), in the event that a product claim is found to be allowable, a method of use claim and a method of making claim ***which is/are of the same scope as the allowed product claim*** may be rejoined with the allowed product claim.

8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached at (703) 305-3399. The fax phone number for responses to be filed BEFORE final rejection is (703) 872-9306. The fax phone number for responses to be filed AFTER final rejection is (703) 872-9307.

Questions which are NOT RELATED TO THE EXAMINATION ON THE MERITS, should be directed to **TC 1600 CUSTOMER SERVICE** at **(703) 308-0198**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

December 31, 2002


Mary E. (Molly) Ceperley
Primary Examiner
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